

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

04 10574 JLT

**BECTON, DICKINSON and COMPANY**

**Plaintiff,**

**V.**

**THERASENSE, INC.**

**Defendant.**

**MAGISTRATE JUDGE**

**CIVIL ACTION NO.**

RECEIPT # 64191  
AMOUNT \$ 150  
SUMMONS ISSUED yes  
LOCAL RULE 4.1  
WAIVER FORM  
MCF ISSUED  
BY DPTY. CLK. F.O.M  
DATE 3/24/04

**COMPLAINT**  
**(Jury Trial Demanded)**

Becton, Dickinson and Company (“BD”) brings this action to obtain a declaratory judgment that (i) BD’s manufacture, use, offer for sale, and sale of its BD Latitude™ Diabetes Management System and BD Logic™ Blood Glucose Monitor do not infringe any valid claim of the United States Patent Nos. 6,143,164 (“the ‘164 patent”) and 6,592,745 (“the ‘745 patent”); and (ii) the ‘164 or ‘745 patents are invalid.

## THE PARTIES

1. BD is a New Jersey corporation with its principal executive offices at 1 Becton Drive, Franklin Lakes, New Jersey. BD has facilities throughout the United States, including in Bedford, Billerica, Boston, Lynn, Mansfield, and Waltham, Massachusetts.

2. TheraSense, Inc. ("TheraSense") is a Delaware corporation with its principal place of business at 1360 South Loop Road, Alameda, California. Upon information and belief, TheraSense regularly conducts business in Massachusetts.

### **JURISDICTION AND VENUE**

3. This Court has jurisdiction over BD's claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
4. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391.

### **FACTUAL ALLEGATIONS**

#### **BD's Blood Glucose Monitoring Products**

5. Diabetes is a prevalent health issue in the United States, with approximately 17 million Americans suffering from the disease. Accurate and consistent monitoring of blood glucose levels is essential to managing the disease, and can help prevent complications such as heart and kidney disease, blindness, stroke, and amputations. For those who must monitor blood glucose levels daily, or even several times a day, the process can be painful and time-consuming.
6. In January 2003, BD introduced two blood glucose monitoring products for sale in the United States--the BD Logic Blood Glucose Monitor and the BD Latitude Diabetes Management System. Both products feature very thin lancets (the mechanisms used to draw blood from the test site) and test strips that require only a small amount of blood. The products also deliver accurate readings quickly, in only five seconds.
7. Since introducing the BD Logic and BD Latitude products, BD has been actively offering for sale and selling those products to customers throughout the United States.

**The Controversy Between BD and TheraSense**

8. On April 8, 2003, TheraSense wrote BD a letter enclosing a copy of United States Patent No. 6,143,164 (“the ‘164 patent”), which issued on November 7, 2000 and is entitled “Small Volume In Vitro Analyte Sensor.” A copy of the ‘164 patent is attached hereto as Exhibit A. In the April 8 letter, TheraSense stated that “Becton Dickinson’s recently introduced Latitude and Logic brand products clearly infringe one or more of the claims of [the ‘164] patent.” The letter also stated that TheraSense takes “the issue of patent infringement seriously.” At the end of the letter, TheraSense stated that it was “willing to consider licensing Becton Dickinson under the ‘164 patent.”
9. In mid-July 2003, TheraSense advised BD of the July 15, 2003 issuance of United States Patent 6,592,745 (“the ‘745 patent”), entitled “Method of Using a Small Volume In Vitro Analyte Sensor with Diffusible or Non-Leachable Redox Mediator.” A copy of the ‘745 patent is attached hereto as Exhibit B. TheraSense accused BD’s blood glucose monitoring products of infringing the ‘745 patent, and reiterated its position that BD take a license to TheraSense’s patents.
10. BD does not believe that its BD Logic or BD Latitude products infringe the ‘164 or the ‘745 patents (collectively, “the TheraSense patents”), or that these patents are valid. BD has advised TheraSense of its position and the parties have engaged in discussions in an attempt to resolve their dispute. TheraSense nevertheless continues to assert that BD’s blood glucose monitoring products infringe its patents, and the discussions between the parties have terminated.
11. Based on the foregoing, there is an actual, immediate and justiciable controversy between BD and TheraSense as to the infringement and validity of the TheraSense patents.

**COUNT I**

12. BD repeats and incorporates paragraphs 1-12 above as if set forth fully herein.
13. Each of the claims of the '164 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.
14. BD has not infringed, directly, indirectly, or otherwise any valid claim of any of the '164 patent.
15. To resolve the legal and factual questions raised by TheraSense and to afford relief from the uncertainty and controversy which TheraSense's accusations have precipitated, BD is entitled to a declaratory judgment that it does not infringe the '164 patent and that the '164 patent is invalid.

**COUNT II**

16. BD repeats and incorporates paragraphs 1-12 above as if set forth fully herein.
17. Each of the claims of the '745 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.
18. BD has not infringed, directly, indirectly, or otherwise any valid claim of any of the '745 patent.
19. To resolve the legal and factual questions raised by TheraSense and to afford relief from the uncertainty and controversy which TheraSense's accusations have precipitated, BD is entitled to a declaratory judgment that it does not infringe the '745 patent and that the '745 patent is invalid.

**WHEREFORE**, BD respectfully requests that this Court:

Determine and declare that the claims of the '164 patent are invalid;

Determine and declare that the claims of the '164 patent are not infringed by BD;

Determine and declare that the claims of the '745 patent are invalid;

Determine and declare that the claims of the '745 patent are not infringed by BD;

Award BD costs of this action, including reasonable attorneys fees; and

Grant such other further relief as the Court deems appropriate.

**DEMAND FOR JURY TRIAL**

BD demands trial by jury on all issues so triable.

BECTON, DICKINSON AND COMPANY

By its attorneys,



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Dated: March 23, 2004